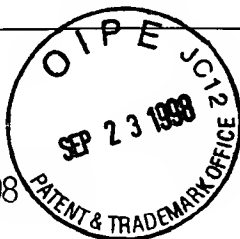




DEPARTMENT OF HEALTH & HUMAN SERVICES



SEP 18 1998

Food and Drug Administration
Rockville MD 20857

Re: Differin Solution (5,212,303)

Docket No. 96E-0353

RECEIVED

SEP 29 1998

PATENT EXTENSION
A/C PATENTS

#14

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,212,303 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The patent claims the human drug product Differin Solution (5,212,303) (adapalene), New Drug Application NDA 20-338.

In the January 2, 1997, issue of the Federal Register (62 Fed. Reg. 101), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before July 1, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Norman H. Stepno
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

ASSISTANT
COMMISSIONER
FOR PATENTS

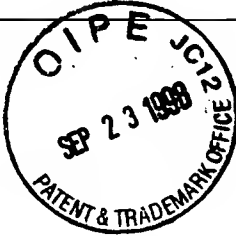
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DEPARTMENT OF HEALTH & HUMAN SERVICES

9200

SEP 18 1998



Food and Drug Administration
Rockville MD 20857

Re: Differin Topical Gel (5,212,303)
Docket No. 96E-0355

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

RECEIVED
SEP 29 1998
PATENT EXTENSION
A/C PATENTS

#14

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,212,303 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The patent claims the human drug product Differin Topical Gel (5,212,303) (adapalene), New Drug Application NDA 20-380.

In the January 28, 1997, issue of the Federal Register (62 Fed. Reg. 4064), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before July 28, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

ASSISTANT COMMISSIONER
FOR PATENTS

90 SEP 29 PM 2:50

cc: Norman H. Stepno
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404



Food and Drug Administration
Rockville MD 20857

Re: Differin Topical Gel (5,212,303)
Docket No. 96E-0355

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

RECEIVED
SEP 22 1998
PATENT EXTENSION
A/C PATENTS

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,212,303 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The patent claims the human drug product Differin Topical Gel (5,212,303) (adapalene), New Drug Application NDA 20-380.

In the January 28, 1997, issue of the Federal Register (62 Fed. Reg. 4064), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before July 28, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

ASIS
FOR PATENTS
98 SEP 22 11 10

cc: Norman H. Stepno
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date:

From: **Brian J. Malkin, Associate Director for Patents and Hearings**
Health Assessment Policy Staff (HFY-20)

Subject: **Patent Term Restoration Application**
for Differin Topical Gel (5,212,303)

To: **Dockets Management (HFA-305)**

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Number **96E-0355** stating that this particular patent is eligible for regulatory review. The Patent Number is **5,212,303**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

98 SEP 22 AM 11:00
ASSIS. INVT. OFFICE
FOR PATENTS